IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SPD SWISS PRECISION DIAGNOSTICS GMBH, v. CHURCH & DWIGHT CO., INC. AND CONSOLIDATED ACTIONS	Case Nos.: 3:09-CV-01802 (MAS)(TJB) 3:10-CV-00276 (MAS)(TJB) **DECLARATION OF ANTHONY R. SCIALLI, M.D. IN SUPPORT OF THE SUMMARY JUDGMENT MOTION OF CHURCH & DWIGHT CO., INC.**

I, Anthony R. Scialli, M.D., hereby declare:

1. I am a medical doctor board certified in obstetrics and gynecology by the American Board of Obstetrics and Gynecology. I currently practice obstetrics and gynecology at George Washington University Hospital in Washington, D. C. I also currently hold a number of academic and professional positions, including Clinical Professor in Obstetrics and Gynecology at George Washington University School of Medicine; Adjunct Professor of Obstetrics and Gynecology at Georgetown University School of Medicine; Adjunct Professor of Pharmacology and Physiology at Georgetown University School of Medicine; Senior Scientific Advisor at Tetra Tech Sciences; Director of the Reproductive Toxicology Center in Washington, D. C.; and, Special Government Employee at the U. S. Food and Drug Administration (FDA). I submit this declaration in support of the summary judgment motion of Church & Dwight Co., Inc. ("Church & Dwight"). I make this declaration of my own personal knowledge except where otherwise stated, and, if called as a witness, I could and would testify competently as set forth below.

2. I obtained my Doctor of Medicine degree at Albany Medical College in 1975. I also obtained my Bachelor of Science degree in biology at Rensselaer Polytechnic Institute the same year. Upon graduating from medical school, I completed a residency in obstetrics and gynecology at George Washington University where I became the Chief Resident of Obstetrics and Gynecology. After my residency, I completed a fellowship in reproductive toxicology at the Reproductive Toxicology Center at Columbia Hospital for Women in Washington, D.C.

3. For more than 36 years, I have studied, researched, published, and lectured in the areas of obstetrics, gynecology and reproductive toxicology. I have been the principal investigator in approximately 20 studies concerning obstetrics and gynecology. As a result of my work in one or more of these areas, I am familiar with immunoassays used to detect the pregnancy hormone human chorionic gonadotropin ("hCG").

4. Attached as Exhibit A is a true and correct copy of a study report, without appendices, dated December 15, 2011, entitled Clinical Sensitivity Study with First Response Gold Digital Pregnancy Test, Clearblue Easy Digital Pregnancy Test, and First Response Early Result Pregnancy Test Using Early Pregnancy Urines ("Study Report").

5. I was the Principal Investigator for the clinical study described in the Study Report ("Georgetown University Medical Center Clinical Study"). I was responsible for the overall conduct of the study, including data analysis and preparation of the Study Report.

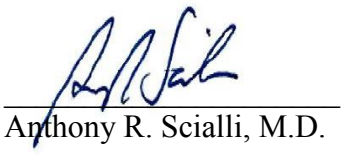
6. The objective of the Georgetown Clinical Study Georgetown University Medical Center Clinical Study was to independently confirm the claimed clinical sensitivity of 4 days before the expected menstrual period ("EMP") for First Response

Gold Digital Pregnancy Test ("FR Digital 5-day"), Clearblue Easy Digital Pregnancy Test ("Clearblue Digital") and the claimed clinical sensitivity of 5 days before the expected menstrual period for First Response Early Result Pregnancy Test ("FR Analog 6-days"). The study included two versions of the FR Digital 5-day – the "old" version manufactured by Acon Laboratories and the "new" version manufactured by Scantibodies Laboratory Inc.

7. The Georgetown University Medical Center Clinical Study used the same urine samples and the same methodology for calculating the day of EMP for all of the devices tested in the study.

8. The study results are set forth on page 7 of the Study Report. These results show that at 5 days before the missed menstrual period ("MMP") (4 days before EMP) the FR Digital 5-day (new) and FR Digital 5-day (old) detected pregnancy in 83.3% and 91.7% of urines respectively. In contrast, at 5 days before MMP (4 days before EMP), the Clearblue Digital detected pregnancy in 75% of urines tested. These results also show that at 6 days before MMP (5 days before EMP) the FR Analog 6-day detected pregnancy in 91.5% of urines.

I declare under the penalty of perjury that the foregoing is true and correct. Executed August 14, 2014, at Washington, D.C.



Anthony R. Scialli, M.D.

Exhibit A

Clinical Sensitivity Study with First Response® Gold Digital Pregnancy Test, Clearblue® Easy Digital Pregnancy Test, and First Response® Early Result Pregnancy Test Using Early Pregnancy Urines

Study site:	Lombardi Cancer Center Georgetown University Medical Center 3800 Reservoir Rd NW Washington DC 20007
Principal Investigator:	Anthony R. Scialli, M.D. Adjunct Professor of Obstetrics and Gynecology and of Biochemistry and Molecular Biology Georgetown University Medical Center and Principal Scientist Tetra Tech Sciences 2200 Wilson Blvd Suite 400 Arlington VA 22201
Sponsor:	Church & Dwight Co., Inc. Princeton, N.J.
Report date:	December 15, 2011

Anthony R. Scialli, M.D.

Clinical Sensitivity Study with First Response® Gold Digital Pregnancy Test, Clearblue® Easy Digital Pregnancy Test, and First Response® Early Result Pregnancy Test Using Early Pregnancy Urines

Table of contents

Contents

Objective

The objective of this study was to independently confirm the claimed clinical sensitivity of 4 days before the expected menstrual period (EMP) for First Response® Gold Digital Pregnancy Test and Clearblue® Easy Digital Pregnancy Test and the claimed clinical sensitivity of 5 days before the expected menstrual period for First Response® Early Result Pregnancy Test.

Test materials

The following materials were provided by the sponsor:

First Response® Gold Digital Pregnancy Tests (the old test kit) Lot number DQO154DO34

First Response® Gold Digital Pregnancy Tests (the new test kit) Lot number BU1160GA

Clearblue® Easy Digital Pregnancy Tests Lot number HEN119/1C

First Response® Early Result Pregnancy Tests Lot number BU1152DC

Product package inserts for each pregnancy test were provided to laboratory personnel

Clinical urine specimens (n = 524) from 48 conceptive cycles that occurred in 48 different women between January, 2007 and May, 2011 were delivered to the laboratory frozen in 15- or 20-mL vials and were maintained at –20 C until the afternoon prior to testing. The urine samples included a sample collected on the day of the EMP, calculated by adding 15 to the day of the luteinizing hormone (LH) peak. The day of the LH peak was determined prior to study start using the Immulite 1000 Immunoanalyzer (Siemens Medical Solutions Diagnostics) and was identified by the Sponsor. Human chorionic gonadotropin (hCG) concentrations were measured in urine samples using the Immulite 1000 Immunoanalyzer prior to study start, and these concentrations were provided by the Sponsor (Appendix 1). Dating of the samples was expressed with respect to EMP using a negative number for days before EMP and positive numbers for days after EMP. For example, EMP–2 refers to two days before EMP.

The urine samples provided for this study consisted of daily urine samples from each of the 48 conceptive cycles beginning two days before hCG was detectable and ending one day after EMP (EMP+1), which is the date of the missed menstrual period. One sample from three days before EMP (EMP–3) was noted on the Sponsor's inventory as not available; however, this notation should have been not tested for hCG. The sample was available and was tested in this study. There was no EMP–1 sample for one of the subjects, no EMP–9 sample for another subject, no EMP–11 sample for a third subject, and no EMP+1 sample for each of three other subjects.

Test procedure

Urine samples (n = 524) were received frozen in the laboratory on July 13, 2011. Four of the sample vials were damaged, and contents were transferred to new vials. The samples in damaged vials were from four different subjects on EMP–10, EMP–7, EMP–2, and EMP, respectively. After the samples were inventoried, laboratory-generated bar-coded numbered labels were